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EXAMINER	
GORDON, BRIAN R	
ART UNIT	**PAPER NUMBER**
1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/870,321	LEHMANN, VOLKER	
	Examiner	Art Unit	
	Brian R. Gordon	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01-19-07*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed January 19, 2007 have been fully considered but they are not persuasive.

In view of applicant's remarks the examiner asserts a pipette including any (in particular a porous plate (plate with hole(s)/apertures) or a permeable membrane such as a filter) of the "diaphragm" elements as defined by the definitions provided by applicant would meet the limitations of the pipette element including a diaphragm.

Applicant states on page 6 of the remarks, "It could be that the pump is adjusted such or is just able to produce a reduced (negative) pressure that is just above the critical pressure, thereby not requiring a controller." Applicant fails to provide where such support of the pump alone having such ability. In fact, applicants paragraph 0029 contradicts such by disclosing "means of a pump controller which controls a pump producing the reduced pressure in the capillary device" While the claim further relates the pumps ability to a critical pressure, there is no numerical value given as for one to ascertain or determine what is the value of such critical pressure, thereby determining the specific limitations of the pump. The cited critical pressure would be dependent upon a number of factors (as supported by a the equation cited in the claims), including but not limited to a specific liquid and its chemical and physical characteristics, the size of the one pore, the physical and chemical characteristics of the diaphragm, the environmental pressure in which one actually performs the "taking up" or aspiration. Considering such, as previously stated any pump capable of generating a negative

pressure in a pipette would be considered equivalent to the element as claimed. In view of such claim 37 directed to such critical pressure is not further structurally limiting of the structure. It should further be noted that the applicant agreed with the examiner comments directed to that of the cited "radius". If should further be noted the general equation, which for calculating a pressure, cited in the claims is not a structural limitation of the device.

Applicant acknowledges the difficulty in understanding the invention due to the different meanings of the term "diaphragm". Applicant asserts the invention is directed to two embodiments and appears to acknowledge the claims as being directed to the second embodiment (Fig. 4) including diaphragm 406.

Applicant has amended the preamble of the claim to recite "a capillary apparatus for taking up a medium to be analyzed". While the preamble is considered proper, it should be noted that the preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. In other words, the preamble expresses a function or purpose for which one intends for the device to be employed. It is only required that the prior art disclose the pipette and pump as stated above. What one intends to do with the medium has no patentable weight on the structure of the capillary apparatus.

Applicant further asserts claims 39 and 45 are supported in paragraph 0098. Paragraph 0098 states

"It is of course also possible, in the case of a hydrophobic diaphragm 406, similarly to pump a predefinable gas by means of the arrangement described above and to prevent entry of liquid through the respective pore, in general through a capillary."

In other words the paragraph supports the device interacting with gas while preventing a liquid from entering. On the other hand, the claims imply the device is capable of taking up any other substance (see rejection for examples) other than the previously mentioned liquid. The device is not disclosed as having such ability. The device is disclosed in a method of pump only a gas or liquid. As previously stated the negative limitation is not adequately supported.

As previously stated the "medium" is not positively claimed as an element of the device and is only mentioned in terms of expressing intended use of the device. In view of such claims 38 and 39 are not further limiting of the structure. Applicant states a working example directed to water is given in paragraph 0093. It should be noted that while the claims are interpreted in light of the specification limitations from the specification are not read into the claims. Even if the structure were recited as being employed with water. Reciting water would not further limit the structure. The medium/fluid which the device aspirates/takes up is not an element of the capillary apparatus. Furthermore the liquid mentioned in the claim as being located at the pore is not an element of the capillary apparatus. The text within the claim directed to such

describes what is intended to occur if one submerges the apparatus in a liquid as illustrated in Figure 4.

As to the prior art, applicant asserts, "Three elements have to be present and interact: a diaphragm with a pore, a liquid at the pore, and a reduced pressure not exceeding the surface tension of the liquid present at the pore."

It should be noted as stated above in terms of the device, the invention is only defined by a pipette including a diaphragm with a pore, and a pump capable of creating a negative pressure. As previously stated the liquid (and or medium) is not an element of the device.

In view of the above remarks, the rejections repeated herein are hereby maintained.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 35-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It should be noted the affect in which a pump is going to have on a liquid present in the device will depend from a number of factors, including pore size, the type of

particular liquid (viscosity), the type of material the diaphragm is manufactured from, surface tension of such material (is it hydrophobic or hydrophilic in reference to the particular liquid). As such, the device as claimed would not function. It is further unclear what is the purpose of such a device and method for if the negative pressure does not allow for liquid to be transferred, therefore nothing occurs. If the device is placed in a first liquid (as illustrated in Figure 4) by the device does not allow the first liquid to enter, then is it applicant's position that a gas (or second liquid) enters instead of the first liquid? If so then where is such gas (or second liquid) located? Figure 4 only illustrates a single liquid. How is it possible for a second substance to enter the pipette when it is submerged in the liquid?

3. Claims 35-46 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A controller is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The pump alone does not function as to control the pressure as claimed.

4. Claims 39-40 and 45-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 39 and 45 are directed to a new negative limitation not previously required. Where is such a claimed supported? If the medium is not liquid, then that implies the medium can be any other material such

as gas, plasma, solid material such as fine powders, suspensions, etc. The medium should be claimed as positively of what it is rather than what it is not. In this case as stated above the medium as disclosed in the application is limited to gas or liquid.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 35-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear how the apparatus is a capillary device when no capillary element is claimed.

The phrase citing at least one pore of a given radius is unclear. The phrase "a given radius" is not a specified dimension as to determine what exactly is the dimension of the pore. A given radius can be any radius one chooses, for the claim places no limitations on the radius.

As to the claims citing the pump produces a negative pressure that does not go below a critical pressure to overcome liquid in the pore, the examiner asserts any vacuum pump or pump capable of creating a negative pressure is equivalent to the claimed pump for any pump can produce a negative pressure that will be lower than the critical pressure of some medium that exists.

It should be noted the effect in which a pump is going to have on a liquid present in the device will depend from a number of factors, including pore size, the type of particular liquid (viscosity), the type of material the diaphragm is manufactured from,

surface tension of such material (is it hydrophobic or hydrophilic in reference to the particular liquid). Without specifying the factors as stated above the device and method as claimed will not function.

The equation of claims 37 and 43 are not further limiting of the structure, but merely states how one intends to calculate the critical pressure.

Claim 38 is directed to how the device is intended to be used. The medium is not positively claimed as an element of the invention.

Claims 39 and 45 are directed to a negative limitation which implies medium can be any other medium other that liquid. This is not supported by the specification.

As to claim 41, there are steps missing. The first step is providing the pipette, however while the second step is directed to producing a reduced pressure in relevance to a liquid. It is unclear where the liquid comes from and how it is related to the pipette. Is the liquid present in the pipette? Is the pipette placed in the liquid? If the pipette is placed in the liquid, but however such liquid is not taken up then how does one classify the method as a method of taking up a medium when the claim doesn't recite any medium ever entering the pipette? The method appears to have no practical use for what is the point of submerging a pipette in a liquid that is not aspirated as well as there is no indication that any other substance is aspirated as well.

Claims 43-46 are not process limitations, for the claims do not add any additional steps to the method.

Claim Interpretations

7. For the purpose of examination, a system comprising an aspirating or vacuum device including a porous structure (filter, frit, membrane, disc with a hole/aperture, etc.) and pump capable of producing a negative pressure is considered equivalent to the device as claimed by applicant.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 35-46 rejected under 35 U.S.C. 102(b) as being anticipated by Bjorkman, US 4,642,220.

Bjorkman discloses a device for carrying out an analysis method. The device includes vessels 2 (pipettes) and the recesses 6 when the reaction vessels 2 are placed in the rack. In this way there is formed a plurality of chambers 8, which upwards are delimited by the porous bottom elements 3. Downwards the chambers 8 are connected to the channel 4. By using the connecting nipple 5, the channel 4 may be connected to

a pressure regulating system (controller/mechanical control unit 25), e.g. to a suitable pump system for controlling the pressure of the chambers 8.

FIGS. 2 and 3 show two different types of reaction vessels, both of which have a porous bottom element 3. In addition thereto the vessel of FIG. 3 has a filter 9, which is applied to and covers the pores of the bottom element 3. For aqueous liquid phases the preferred filter is hydrophilic, particularly a three dimensional depth filter.

We have found that hydrophobic membranes with pore sizes from about 1μ to 20 μ are useful for the reaction vessels shown in FIG. 2, especially when biospecific reactions are involved. It is suitable to work with pressure differentials between 100 and 500 Pa when using these types of porous bottoms (column 2, line 58).

10. Claims 35-46 rejected under 35 U.S.C. 102(b) as being anticipated by Moulton US 5,851,491.

Moulton discloses A filter (diaphragm) for a pipette tip is provided, comprising a plurality of vertically-oriented cylindrical micro fibers cohesively bundled in adjoining columns which are composed of a core of an autoclavable material and an outer coating of a hydrophobic material. The micro fibers are packed together such that each micro fiber is compressed against the other fibers and the inner surface of the pipette tip. The compression of the fibers creates vertically-oriented pores interstitially between the micro fibers, each pore having a pore size at various points within the filter (abstract).

Filter 30 comprises a plurality of cylindrical micro fibers 44. Referring to FIGS. 3 and 4, micro fibers 44 each comprise a core 46 of an autoclavable material and an outer

coating 48 of a hydrophobic material. In a first preferred embodiment, core 46 is formed of polypropylene and outer coating 48 is formed of polyethylene.

Pipettor 22 may be any suction device capable of drawing fluid 26 into pipette tip 12 in incremental amounts, including volumetric pipettors, elastic bulbs, bellows, or suction pumps.

11. Claims 35-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Kitajima et al., US 6,225,130.

12. Kitajima et al. disclose a method of preparing a serum sample from whole blood without destroying blood cells, and thereby, of obtaining highly reliable analytical values. The inventors found that, there is a critical value between the insertion speed of a serum suction nozzle into a vessel and a suction pressure, and a blood serum sample can be obtained without destruction of blood cells by sucking the blood serum while keeping the suction pressure under the critical value (Summary of Invention).

The holder body 10 (pipette) is made of high-impact polystyrene resin, and has a glass fiber filter chamber 11 for containing the glass fiber filter 30 and a microporous membrane chamber 12 for containing a polysulfone microporous membrane as the microporous membrane 40 above the glass fiber filter chamber 11. The microporous membrane has a diameter greater than the glass fiber filter chamber, and the periphery of the microporous membrane 40 is nipped by the step portion 19 formed on the foundary between the glass fiber filter chamber 11 and the microporous membrane chamber 12 and the bottom of the cap 20 so as not to form a leakage without passing the blood filtering material.

As disclosed in the examples suction was carried out by using a peristaltic pump at a suction pressure (pressure difference) of 300 mm Hg at the maximum for a suction period of 15 seconds.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

brg

BRIAN R. GORDON
PRIMARY EXAMINER